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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,840	01/21/2005	Jane Daun	2003946-0091 (IKKI/US)	8954

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CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER	
OWENS, AMELIA A	
ART UNIT	PAPER NUMBER
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,840	DAUN ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32,60 and 88-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32,60-88-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *NO DRAWINGS*.

DETAILED ACTION

1. Claims 1-32,60,88-100 are pending.

Information Disclosure Statement

2. The IDS filed 8/26/2005 has not been considered as it contains duplicate items.

3. The IDS filed 3/30/2006 and 7/7/2204 have been considered.

Election

4. Applicant's election with traverse of group I, claims 1-28 in the reply filed on November 14, 2006 is acknowledged. Applicants further elected a species, compound 112 on page 52 of the specification.

5. Per applicants request, the restriction has been considered. The restriction requirement has been withdrawn and all claims examined. Claims 1-32,60,88-100 have been examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim employs the term 'derivative' which is ambiguous since derivative is referring to material "derived" from the named formula. Applicants' reagent or material or product 'is' the claimed formula. Therefore, it is recommended that the term 'derivative' be replaced with the term 'compound' to be consistent with the named formula.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 29-32,60,88-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

The specification does not enable any physician skilled in the art of medicine, to make the invention commensurate in scope with these claims. The how to make requirement of the enablement statute, when applied to process claims, refers to operability and how to make the claimed process work. "The [eight] factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. The main issues are the correlation between clinical efficacy for treating an inflammatory or autoimmune or proliferative disorder using the claimed compounds.

a) Determining if any particular claimed compound would treat any particular disease would require synthesis of the compound, formulation into a suitable dosage form, and subjecting it clinical trials with a number of fundamentally different diseases described in the claims and by the language - treating inflammatory or autoimmune or proliferative disorder and to testing them in an assay known to be correlated to clinical efficacy of such treatment. This is a large quantity of experimentation. b) The direction concerning treating inflammatory or autoimmune or proliferative disorder is found in specification at paragraph 61, which merely states Applicants' intention to do so. Applicants describe formulations at paragraph 78 and 83. Doses required to practice their invention are described at paragraph 96. There are no guidelines for determining the doses needed to provide an autoimmune disorder effect *vs.* a proliferative disorder *vs.* an inflammatory disorder effect. Are the identical doses to be used for treating these unrelated *classes* of diseases? Further, there are no guidelines for determining the doses needed to provide

an inflammatory disorder effect where the inflammatory disorder for example is multiple sclerosis vs. asthma vs. psoriasis, etc. This extends likewise to autoimmune and proliferative disorders. There is an assay described at paragraph 300. With no data it is unclear if this assay is correlated to treating any particular inflammatory or autoimmune or proliferative disorder. c) There is no working example of treatment of any disease in man or animals. d) The nature of the invention is treating an inflammatory or autoimmune or proliferative disorder which involves physiological activity. e) The state of the clinical arts is that deazapurines have been tested to determine their inflammatory effect but further study is needed. See Krenitsky et al, Imidazo[4,5-c]pyridines (3-Deazapurines) and Their Nucleosides as Immunosuppressive and Antiinflammatory Agents, J. Med. Chem. 1986, 29, 138-143 @ page 141 column 1 5th full paragraph. See also USP 3891660 column 5 line 45. Note the patent while considering mammals does not include humans.

f) The artisan using Applicants invention would be a physician with a MD degree and several years of experience. g) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.*, 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain). h) The scope of the claims involves all of the thousands of compounds of claims as well as the hundred of diseases embraced by the language treating an inflammatory or autoimmune or proliferative disorder. Thus, the scope of claims is very broad.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the

claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 11/344534. Although the conflicting claims are not identical, they are not patentably distinct from each other because USSN 534 discloses species 112 as elected and instantly claimed and its use to treat an inflammatory, autoimmune or proliferative disorder.

One of ordinary skill in the art would thus be motivated to prepare compounds from under the USSN 534 in order to obtain additional beneficial inflammatory, autoimmune or proliferative agents. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of USSN 534 in the expectation of obtaining a useful compound to treat an inflammatory, autoimmune or proliferative disorder as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in In re Lohr 137 USPQ 548 at 549 (CCPA 1963), and in In re Payne 204 USPQ 249 at 254 (CCPA 1979).

9. Claims 60,88-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No.

10/753261. Although the conflicting claims are not identical, they are not patentably distinct from each other because USSN 261 discloses species 112 as elected and instantly claimed and its use to treat bone metastasis, a type of proliferative disorder.

One of ordinary skill in the art would thus be motivated use the claimed compounds to practice the method from under the USSN 261 as the method and compound employed therein are the same. USSN 261 clearly places the instant method before the artisan. The level of skill in the art is further reflected in In re Lohr 137 USPQ 548 at 549 (CCPA 1963), and in In re Payne 204 USPQ 249 at 254 (CCPA 1979).

For above ODP paragraphs, this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Amelia A. Owens
Primary Examiner
Art Unit 1625